IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **Ethicon Wave 1 cases listed in Exhibit A**	

PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO EXCLUDE THE GENERAL CAUSATION OPINIONS OF DEFENSE EXPERT MICHAEL P. WOODS, M.D.

The proffered general causation/liability opinions of Michael P. Woods, an expert for the Defendants, fail to pass the *Daubert* standard. Dr. Woods is not qualified to discuss design issues regarding Defendants' TVT and TVT-O mesh slings because he has extremely limited knowledge of the design process. Dr. Woods also lacks the expertise to opine about the whether the warnings in those products' Instructions for Use ("IFU") were sufficient. As to methodology, Dr. Woods's opinions are unreliable because he did not review any of the key documents that would have explained Ethicon's design procedures, because he reached opinions about the TVT's design without considering the design protocols, and because his complication rates are based on numbers that exist only in his head. For all of these reasons, Dr. Woods should be excluded from giving the two opinions that form the foundation of his analysis.

Defendants previously proffered Dr. Woods as a TVT expert in the *Mullins* consolidation. His report for Ethicon Wave 1 also includes opinions about the TVT-O, but in

many instances, Dr. Woods simply adjusted his TVT report to add a reference to the TVT-O.[1] In Mullins, Plaintiffs filed a motion to exclude Dr. Woods from testifying. As of the filing of this motion, the Court had not ruled on that motion. Because there has been no major change in Dr. Woods's opinions, his qualifications, or his methodology, this brief will make several arguments that parallel those made in *Mullins*.

As Dr. Woods demonstrated during his TVT deposition, he does not have the qualifications to give opinions about product design or about warnings, and he did not use a reliable methodology in reaching his opinions.

LEGAL STANDARD

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. On the issue of qualifications, "the district court must decide whether the expert has 'sufficient specialized knowledge to assist the jurors in deciding the particular issues in the case.'" *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999)).

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents "scientific knowledge," meaning that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury—i.e., whether it is relevant. *United States v. Dorsey*, 45 F.3d

[1] Woods TVT-O Dep., March 31, 2016, portions attached as Exhibit B, at 27:6-14.

809, 813 (4th Cir. 1995). The relevance aspect of the inquiry is often discussed in terms of whether the expert's opinions "fit" the case. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

To meet the standard of reliability, the testimony "must be supported by appropriate validation—i.e., 'good grounds,' based on what is known. In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1383 (4th Cir. 1995).

There are five factors courts often consider, taken from the *Daubert* opinion, in assessing the reliability of expert testimony:

- (1) whether the testimony has been tested,
- (2) whether it has been published or exposed to peer review,
- (3) its rate of error,
- (4) whether there are standards and controls over its implementation, and
- (5) whether it is generally accepted.

See Cavallo v. Star Enterprise, 100 F.3d 1150, 1158 (4th Cir. 1996). However, "the factors discussed in *Daubert* were neither definitive, nor exhaustive." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

Courts should focus on expert witnesses' "principles and methodology, not on the conclusions that they generate." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). This is because "*Daubert* governs whether evidence is admitted, not how persuasive it must be to the factfinder." *Cavallo*, 100 F.3d at 1158.

ARGUMENT

There are several reasons that this Court should prohibit Dr. Woods, a urogynecologist designated as a Defense expert, from giving opinions about the design of the TVT and TVT-O, or about product warnings. Dr. Woods's report touches on several topics, but he has two general opinions:

- "TVT and TVT_O are Reasonable Safe for its [sic] Intended Use, the Benefits Outweigh the Risks, and Complications are Acceptably Low Compared to Alternative Products."[2]
- "The TVT and TVT-O IFUs Adequately Warn of the Risks Associated with the Products."[3]

The first bullet point does not use the word "design," but it clearly is an opinion about the product's design. The first clause recites the legal test on a design defect claim in West Virginia. *See Morningstar v. Black & Decker Mfg. Co.*, 253 S.E.2d 666, 683 (W. Va. 1979) (stating that "the general test for establishing strict liability in tort is whether the involved product is defective in the sense that it is not **reasonably safe for its intended use**" (emphasis added)). Thus, it is a left-over opinion from *Mullins*, a case that focused only on design issues. The second clause addresses the risk-utility test, which the focus of the design defect inquiry in many states. *See, e.g.*, *Beard v. Johnson & Johnson, Inc.*, 41 A.3d 823, 836 (Pa. 2012); *Branham v. Ford Motor Co.*, 701 S.E.2d 5, 14 (S.C. 2010); *Mikolajczyk v. Ford Motor Co.*, 901 N.E.2d 329, 352 (Ill. 2008), *opinion modified on denial of reh'g* (Dec. 18, 2008); *Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 258 (Tex. 1999); *Halliday v. Sturm, Ruger & Co.*, 792 A.2d 1145, 1150 (Md. Ct. App. 2002); *Cavanaugh v. Skil Corp.*, 751 A.2d 564, 580 (N.J. Super. App. Div. 1999), *aff'd*, 751

[2] Woods Report for Ethicon Wave 1, attached as Exhibit C, at p. 19.
[3] *Id.* at 84.

A.2d 518 (N.J. 2000). The last clause addresses the utility of alternative designs, which generally factor into the design defect analysis in some manner. *See, e.g.*, *Branham*, 701 S.E.2d at 14; *Hernandez*, 2 S.W.3d at 258; *Halliday*, 792 A.2d at 1150.

The second opinion clearly goes to the issue of warnings. This Court should preclude Dr. Woods from opining about either design issues or about warnings, for the reasons stated below.

I. Dr. Woods should be precluded from giving design opinions because he did not review the key Ethicon documents related to product design, he has no knowledge about the design process, and he relies on personal complication rates that cannot be quantified.

Dr. Woods's deposition testimony reveals that he is not qualified by "knowledge, skill, experience, training, or education" to give opinions about the design of medical devices such as the TVT and TVT-O. Dr. Woods's personal experience with the design of medical devices is limited to consulting on one aspect of one device many years ago.[4] His deposition further reveals that he does not have the necessary knowledge or education to give a reliable opinion about product design.

A. Dr. Woods largely ignored Ethicon's internal documents, and he demonstrated a complete lack of knowledge regarding the product design process.

This Court has previously recognized the importance of reviewing internal documents before giving opinions on design issues. *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *14 (S.D. W. Va. Apr. 24, 2015) (excluding expert's design opinions on design protocols because he had failed to review internal documents). In his TVT deposition, Dr. Woods emphatically stated that he did not review any internal documents in formulating his opinions.

> Q. Okay. So you did not consider the Ethicon internal documents when forming your opinions that you're here to talk about today?

[4] Woods TVT Dep., Oct. 5, 2015, portions attached as Exhibit D, at 94:20-95:8.

A. Absolutely not.[5]

Dr. Woods insisted that he instead relied on "evidence-based data."[6] When asked precisely whether he had reviewed any "Ethicon internal design documents" in forming his opinions, Dr. Woods again said "no."[7] In his TVT-O deposition, Dr. Woods stated that he had reviewed some internal documents related to the idea that the TVT-O would create less pain than the TVT, but Dr. Woods did not identify or produce the documents he reviewed.[8] His updated report includes only one citation using the coding "ETH.MESH," which is used for Ethicon's internal documents.[9]

Because he did not review the relevant design documents, Dr. Woods lacks the required knowledge to give a reliable opinion about the design of the TVT. For instance, Dr. Woods conceded that he had not read the design history file for the TVT:

> Q. Okay. Did you review the design history file for the TVT Retropubic?
>
> A. I reviewed over -- I don't recall specifically on that. When Ulmsten was first coming out with this, with the integral theory, I found it to be a real challenge to my dogma, for one, but in looking at how he talked about using the various suburethral components, I did look at that.
>
> Q. Okay. Do you know, one way or another, if you reviewed the design history file for the TVT, as we sit here right now?
>
> A. I did not. I do not have a bundle that says that's what it is, no.[10]

As the name suggests, the design history file would include all of the information about the design of the product. The necessary components of a design history file are laid out in 21 C.F.R. § 820. *See* 21 C.F.R. § 820.1 ("The requirements in this part govern the methods used in,

[5] Woods TVT Dep., Ex. D, at 15:15-18.
[6] *Id.* at 15:19-23.
[7] *Id.* at 15:24-16:3.
[8] Woods TVT-O Dep., Ex. B, at 9:22-10:4.
[9] *See generally* Woods Wave 1 Report, Ex. C; *see also* p. 63 n.52. The document that Dr. Woods reviewed related to Ethicon seeking feedback from surgeons regarding changes to the mesh.
[10] Woods TVT Dep., Ex. D, at 99:4-16.

and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use."). Ethicon research and design engineer Katrin Elbert, Ph.D., testified that the design history file is "the archive of all the documents that show us the history of the design of the product. It contains all of our design control documents, and it's also what we use to support regulatory submissions."[11] Dr. Woods's failure to review such important documents leaves him without a reasonable foundation for an opinion about the TVT's product design. In addition, Dr. Woods had not heard of MedScand, which is the company that partnered with Ulf Ulmsten in developing the TVT.[12]

Dr. Woods also could not explain what a failure modes and effects analysis is, or what the purpose of it is. (*Id.* at 99:25-100:7). As discussed in the deposition of Ethicon medical director Charlotte Owens, the purpose of a design failure modes and effects analysis ("dFMEA") is to "review the potential risk associated with the design of the product."[13]

> Q. And when you say "associated with the design of the product," that means that when the product is in a woman's body and the product was manufactured completely consistent with the specifications, these are the things that could go wrong and harm a patient, correct?
>
> A. Correct.[14]
>
> Q. And you understood that it was required that you capture all of the different failure modes, all the things that could go wrong in the procedure, even if the doctor was properly trained and following the proper procedure, and the effects of those failure modes, the hazards that could occur, and the resulting harms, and you were supposed to capture all of them, correct?
>
> A. Yes, all that we could conceive of, yes.[15]

[11] Elbert Dep., Dec. 23, 2014, portions attached as Exhibit E, at 270:5-11.
[12] Woods TVT Dep., Ex. D, at 99:17-20.
[13] Owens Dep., Sept. 13, 2012, portions attached as Exhibit F, at 485:14-24. Ms. Owens's cited deposition related to the Prolift product, not the TVT, but the discussion quoted was not product-specific.
[14] *Id.* at 485:25-486:7.
[15] *Id.* at 449:12-22.

Not surprisingly, Dr. Woods, also could not identify whether product warnings are a component of a dFMEA.[16] Dr. Woods should have reviewed these documents in forming his opinions about the design of the TVT. But not only did he fail to review those documents, he could not even identify the purpose of the failure modes and effects analysis.

In addition, Dr. Woods did not know what a DDSA is.[17] A DDSA is also an important component of the design process. The letters stand for "Device Design Safety Assessment."[18] Part of the DDSA form lists and rates hazards associated with the product.[19] Examples include biocompatibility hazards and hazards from use of the device.[20] Given that he did not know what a DDSA is, Dr. Woods clearly did not review that information for the TVT or TVT-O.

Dr. Woods's lack of knowledge on these points demonstrates that he does not have the expertise necessary to opine about issues of product design, and his failure to review Ethicon's design documents in formulating his opinions was not a reliable methodology.

B. Dr. Woods relies in part on supposedly low complication and high satisfaction rates from his own practice, yet he has kept no records on those points, so these complication and satisfaction rates exist only in Dr. Woods's mind.

Dr. Woods also should be excluded from giving design opinions because he relies in part on supposedly low complication rates from his practice; yet, these rates exist only in Dr. Woods's head. Dr. Woods notes certain complication rates in his expert report. For instance, he says that "[m]y mesh exposure rate is approximately 1%, and my reoperation rate is approximately 3% …."[21] Dr. Woods also states that "[m]esh exposures and erosions, complications unique to TVT compared to native tissue repairs, are complications that can occur

[16] Woods TVT Dep., Ex. D, at 100:12-15.
[17] *Id.* at 100:16-20.
[18] Owens Dep., Ex. F, at 497:20-23.
[19] *Id.* at 498:20-24.
[20] *Id.* at 498:25-499:12.
[21] Woods Wave 1 Report, Ex. C, at 4.

on average in about 1-3% of women … ."[22] In his TVT deposition, Dr. Woods claimed a satisfaction rate of 95 or 96%, among his TVT patients.[23] But further testimony revealed that he had no basis for any of these rates, other than his memory:

> Q. Okay. And when you looked and you put numbers in your expert report of 1 percent erosion rate, 2 to 3 reoperation rate, that's all coming from your head, correct?
>
> A. My data closely reflects the data that's out there, yes.
>
> Q. That wasn't my question. All of those numbers in your report came from your mental estimates as opposed to looking at any hard data or numbers to make those determinations; is that accurate?
>
> A. I would say that that is reasonably accurate.[24]

Dr. Woods further described his estimates as "a ballpark figure that is probably pretty close."[25]

> Q. So this is a mental list?
>
> A. Yes.
>
> Q. So you don't have any list anywhere where you have exact numbers written down on a spreadsheet or piece of paper –
>
> A. No.
>
> Q. -- for the amount you've implanted?
>
> A. No.
>
> Q. Okay. For the amount you've done reoperations on?
>
> A. No.
>
> Q. Okay.
>
> A. I mean, there would probably be some billing records, or something, somewhere where we could look, but...

[22] *Id.* at 23.
[23] Woods TVT Dep., Ex. D, at 141:8-12.
[24] *Id.* at 148:17-149:4.
[25] *Id.* at 219:11-18.

> Q. So you could maybe find that number if you looked for it?
>
> A. Actually, I'm no longer using that billing service and so I'm not sure I could find it using the billing.[26]

That testimony speaks for itself. Dr. Woods is relying in part on complication rates from his own practice, and yet he has no foundation whatsoever for the claimed complication rates. Plaintiffs have no reasonable way of testing the veracity of Dr. Woods's numbers, which exist only in his mind. Because there is no foundation for this testimony, Dr. Woods should, at the very least, be prohibited from testifying about complication rates from his own practice. In addition, this testimony further demonstrates that there is no solid foundation for his general opinions about the safety of the TVT design.

C. Dr. Woods's testimony reveals a fundamental lack of understanding as to the process that companies go through in developing a medical device.

A third major problem with Dr. Woods's opinions about product design is that he has no expertise in product development, and he did no analysis of the development work done by Ethicon with regard to the TVT. Product development is a major component of product design. As stated in this Court's order on consolidation, the West Virginia Supreme Court has written:

> The term "unsafe" imparts a standard that the product is to be tested by what the reasonably prudent manufacturer would accomplish in regard to the safety of the product, having in mind the general state of the art of the manufacturing process, including design, labels and warnings, as it relates to economic costs, at the time the product was made.

(Mem. Op. & Order, *Mullins* Dkt. No. 38, at p. 2 (citing *Morningstar v. Black & Decker Mfg. Co.*, 253 S.E.2d 666, 667 (Syl. ¶ 5) (W. Va. 1979)). Other states have similar rules. *See, e.g.*, Tenn. Code Ann. § 29-28-102(8) (stating that a product is defective if a reasonably prudent manufacturer would not have placed it onto the market).

[26] *Id.* at 147:1-20.

Dr. Woods's testimony reveals that he has no expertise in the process that companies use in developing a new product.

> Q. Do you know what a company research is before a product is designed or released?
>
> MR. SNELL: Form, vague, overbroad, incomplete hypothetical.
>
> BY MR. KUNTZ:
> Q. You can answer.
>
> A. I have vague ideas, but I -- I have no solid regulatory aspect at all.
>
> Q. Okay.
>
> A. I'm usually asked, you know, such as with my work with Ethicon is, "What is your opinion on this?" I worked on a couple of the other – the other, like with TVT Secur, and then looking at some of the evolution ones, but as in the regulation, that is something that's not what I would – I've got other things to be worried about.
>
> Q. You wouldn't consider yourself an expert in that area?
>
> A. Pardon me?
>
> Q. You're not an expert in that area, correct?
>
> MR. SNELL: Form, "that area."
>
> THE WITNESS: I feel that I do not have the knowledge base. I may have a very vague knowledge base but not the level that would be required in manufacturing.[27]

When asked how a company goes about designing a medical device, Dr. Woods stated that "they get an idea, and they do benchtop work, and then it evolves through; and I would say I'm more at the end of that process."[28]

This testimony further illustrates Dr. Woods's lack of knowledge as to the design process, as well as his failure to do the necessary research to inform himself in formulating his

[27] Woods TVT Dep., Ex. D, at 97:7-98:6.
[28] *Id.* at 98:8-15.

opinions. Consequently, he should be excluded from giving opinions about the design of the TVT.

II. Dr. Woods admits that he has no expertise in the area of warnings and instructions, so those opinions should also be excluded.

The final major reason that Dr. Woods should be excluded from giving design opinions is that he has no expertise in the area of product warnings. In fact, Dr. Woods admitted that he has no expertise in product warnings.

> Q. You're not an expert on warnings related to medical devices, correct?
>
> A. No, I would not call myself an expert.
>
> Q. Okay. I mean, you don't know what risk information a medical device company needs to put inside an IFU, do you?
>
> MR. SNELL: Objection, form.
>
> THE WITNESS: I believe that the FDA has very specific guidelines.
>
> BY MR. KUNTZ:
> Q. Okay. You don't know what those are as we sit here today?
>
> A. No, I do not.[29]

Dr. Woods further testified that he had never drafted the IFU for a medical device, and that he had never worked on the warnings for a medical device or a prescription drug.[30]

This Court has previously recognized the importance of an expert's admission that he is not an expert in the area of warnings. In the *Bard* litigation, this Court precluded Dr. Shull from giving warnings opinions because he had testified that "I would not claim to be an expert in that area." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013), *amended on reconsideration in part* (June 14, 2013). This Court also wrote that Dr. Shull "is unqualified to testify on the specific issue of product warnings, as evidenced by his lack of familiarity with the

[29] Woods TVT Dep., Ex. D, at 93:12-24.
[30] *Id.* at 94:3-11.

process." *Id.; cf. Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 704 n.2 (S.D.W. Va. 2014) (allowing Dr. Rosenzweig's testimony on warnings, stating that "Dr. Shull *admitted* that he had not developed product warnings, had no experience in that area, and did not hold himself out as an expert in product warnings. … Dr. Rosenzweig has made no similar admissions."). That same analysis applies here to Dr. Woods, who has admitted that he is not an expert on warnings, and whose testimony demonstrates a lack of familiarity with the process.

In addition, Dr. Woods's report is 85 pages, and he spends a little over one page on the subject of product warnings, without citation to any documents.[31] His opinion is based largely on his own experience with Ethicon seminars, as well as his own perception of the reason for actions by Ethicon and various regulatory agencies. Thus, in addition to being unqualified to opine about warnings, Dr. Woods has failed to demonstrate that his methodology in arriving at his warnings opinions was reliable.

CONCLUSION

For all of these reasons, this Court should preclude Dr. Woods from giving any opinions about the TVT's or TVT-O's product design, including but not limited to the opinions that the TVT and TVT-O are reasonably safe for their intended use, and that the benefits of the TVT and TVT-O outweigh the risks. Dr. Woods's testimony indicates that he not qualified to discuss design issues, because he does not have the necessary "knowledge, skill, experience, training, or education" about the design process. *See* Fed. R. Evid. 702. Dr. Woods did not review Ethicon's key design documents and demonstrated a lack of knowledge about that process generally. Therefore, Dr. Woods does not possess "sufficient specialized knowledge to assist the jurors in deciding the particular issues in the case." *See Belk*, 679 F.3d at 162.

[31] Woods Wave 1 Report at 84-85.

In addition, Dr. Woods's failure to review the key design documents, so as to learn about the design of the product, including the potential hazards, as well as his reliance on complication rates that exist only in his own mind, demonstrate that Dr. Woods did not use a reliable methodology in forming his opinions. In other words, he does not have "good grounds" for his opinions on product design. *See Benedi*, 66 F.3d at 1383.

The Court should also exclude Dr. Woods's warnings opinions. He admits that he is not an expert of warnings, and his report lacks any scientific analysis on warnings.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on April 21, 2016, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

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